SZABO 201.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Andrew Szabo
Serial No.	:	09/400,649
Filed	:	September 21, 1999
For	:	NUTRITIONAL OPTIMIZATION SYSTEM AND METHOD
Examiner	:	Samuel Rimell
Group:		2175

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

May 8, 2007

APPLICANTS REPLY BRIEF UNDER 37 C.F.R. §41.41(a)

Hon. Commissioner of Patents and Trademarks
Washington, D.C. 20231

SIR:

In response to the Examiner's Answer dated March 9, 2007, the time for response to which expires May 9, 2007, Applicant herewith provides its Reply Brief. Applicant has previously requested oral argument, and a copy of the request is provided herewith:

ARGUMENT

In Applicant's Brief, the standard for anticipation was imprecisely presented. Applicant therefore takes this opportunity to present the proper standard which should be applied by the Board. The Federal Circuit restated the applicable law in In Re Omeprazole Patent Litigation 04-1562, -1563, -1589 (Fed. Cir 2007), Sip. Op. at 11: "Anticipation requires disclosure of each and every claim limitation in a single prior art reference, either explicitly or inherently. MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed. Cir. 1999). An anticipation analysis requires a comparison of the construed claim to the prior art. Helifix, Ltd. v. Blok-Lok, Ltd., 208 F.3d 1339, 1346 (Fed. Cir. 2000)."

Thus, the claims must be properly construed, and then the explicit or inherent teachings of the reference applied, to determine whether each and every claim limitation is disclosed.

Claim 29 provides the step of "(d) determining economic parameters associated with the subset of records." Claim 44 provides the step of "(c) determining a statistical risk relating to the set of records and the determined user relevance parameter." Claim 59 provides the step of "(b) determining a statistical risk associated with records within the class of information and the received specification."

It is further noted that claim 44, in contrast to claim 29, requires that the statistical risk related to both the set of records and the determined user relevance parameter. Even assuming *arguendo* that the Examiner's rejection of claim 29 on this point is valid, this additional language is neither taught nor suggested by Mayaud.

The Examiner asserts that "Drug allergies are a statistical risk associate[d] with a record of a drug in a database". However, the Examiner does not indicate how the mere user input of a "fact", i.e., the presence of absence of a drug allergy, corresponds with the method step of "determining a statistical risk associated with a respective record." Mayaud indeed does not apply any statistical methods or analyze any results based on probabilities. The Examiner indicates that because Applicant has not defined "statistical risk" nor provided a suitable definition, that he is free to interpret the language in any way necessary to support the rejection. Indeed, the term "statistical" has been previously defined. To supplement the record, "statistics" is defined as:

- a branch of applied mathematics concerned with the collection and interpretation of quantitative data and the use of probability theory to estimate population parameters
  wordnet.princeton.edu/perl/webwn
- Statistics is the science and practice of developing knowledge through the use of empirical data expressed in quantitative form. It is based on statistical theory which is a branch of applied mathematics. Within statistical theory, randomness and uncertainty are modelled by probability theory. Because one aim of statistics is to produce the "best" information from available data, some authors consider statistics a branch of decision theory. ...
  en.wikipedia.org/wiki/Statistics

Meanwhile, "risk" (within the relevant context) is defined as:

- expose to a chance of loss or damage; "We risked losing a lot of money in this venture"; "Why risk your life?"; "She laid her job on the line when she told the boss that he was wrong"
- the probability of becoming infected given that exposure to an infectious agent has occurred
- gamble: take a risk in the hope of a favorable outcome; "When you buy these stocks you are gambling"
  wordnet.princeton.edu/perl/webwn
- Risk is the potential harm that may arise from some present process or from some future event. It is often mapped to the probability of some event which is seen as undesirable. Usually the probability of that event and some assessment of its expected harm must be combined into a believable scenario (an outcome) which combines the set of risk, regret and reward probabilities into an expected value for that outcome. ...
  en.wikipedia.org/wiki/Risk
- In futures trading Risk, is the probability of loss of trading capital. Market risk may be one of the things considered by fundamental traders but it is not all of it. Market risk if it exists in futures, may not be considered at all by technical traders who base there decisions on price action. Prices move first and fundamentals come second.
  en.wikipedia.org/wiki/Risk_(Futures)
- The probability of harmful consequences, or expected losses (deaths, injuries, property, livelihoods, economic activity disrupted or environment damaged) resulting from interactions between natural or human-induced hazards and vulnerable conditions. Conventionally risk is expressed by the relation Risk = Hazards x Vulnerability.
  www.adrc.or.jp/publications/terminology/top.htm
- The combination of the frequency, or probability, of occurrence and the consequence of a specified hazardous event. NOTE: The concept of risk always has two elements: the frequency or probability with which a hazardous event occurs and the consequences of the hazardous event.
  www.bees.unsw.edu.au/ohs/definitions.html
- The chance or possibility of loss. For example, physicians may be held at risk if hospitalization rates exceed agreed upon thresholds. Potential financial liability, particularly with respect to who or what is legally responsible for that liability. With insurance, risk is shared by the patient and insurance company but the company's risk is limited by the policy's dollar limitations. In HMO's, the patient is at risk only for copayments and the cost of non-covered services. ...
  www.plexisweb.com/glossary/words/r2.html
- The likelihood or probability that a loss of information resources or breach of security will occur.
  www.utmb.edu/is/security/glossary.htm
- The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant.
  www.virginia.edu/vprgs/irbsbsterminology.html
- The probability of injury, disease, or death under specific circumstances. Risk can be expressed as a value that ranges from zero (no injury or harm will occur) to one hundred percent (harm or injury will definitely occur). Risk-based standards limit the risk that releasing a contaminant to the

environment may pose rather than limiting the quantity that may be released.
www.epa.gov/narel/radnet/glossary.html

- The chance of something happening that will have an impact upon objectives. It is measured in terms of consequences and likelihood.
www.riskmanagement.qld.gov.au/info/guide/gls.htm
- This term must not be confused with the term "hazard". It is most correctly applied to the predicted or actual frequency of occurrence of an adverse effect of a chemical or other hazard.
www.bio.hw.ac.uk/edintox/glossall.htm
- A measure of the probability that damage to life, health, property, and/or the environment will occur as a result of a given hazard.
www.nsc.org/ehc/glossar2.htm
- Often defined as the standard deviation of the return on total investment. Degree of uncertainty of return on an asset.
www.clrfn.com/extras/glossary/exglostext.html
- A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food. (The probability and severity of an adverse effect/event occurring to man or the environment following exposure, under defined conditions, to a risk source(s)).
www.fsra.net/glossary.html
- Chance of hazard or bad consequences; exposure to chance of injury or loss. Risk level is expressed in terms of hazard probability and severity.
https://crc.army.mil/RiskManagement/detail.asp
- the variability of returns. Generally, the higher the level of risk an investor is prepared to accept, the higher the potential return over time may be. Find out about managing risk.
www.btonline.com.au/content/resources/glossary.htm

[Contrast with the word "hazard", see above]

Since the determination of a "statistical risk" requires some reference to probabilities or likelihoods relating to an event having uncertain outcome, rather than certainties or presumptions of definiteness, it is clear that the "Drug Allergies" of Mayaud represent a distinct concept not encompassed by this claim language, and is perhaps better described by the word "hazard". Since the word "risk" has accepted meaning, which is clarified by the word "statistical", it is respectfully submitted that due deference to the scope of that meaning is required. Therefore, the Examiner is not free to formulate his own definition which is inconsistent with the specification, claims, and common usage. Applicants provided herewith a list of the first 200 references (of about 76,300) identified by Google for the query "statistical risk". Therefore, applicants respectfully assert that the phrase has a known and accepted meaning in the art., consistent with applicant's assertions.

The Examiner alleges that the output of Mayaud, Fig. 11 "…will include a drug or drugs that have been automatically (by computer) optimized for both the risk to the patient and the economic cost. This is considered to be an automatic optimization since it is performed by the assistance of a computer program, and a joint optimization since it considers two separate

variables (cost and allergic risk)." Assuming *arguendo* that the "statistical risk" determined by respective elements of claims 29, 44 and 59 is somehow disclosed by Mayaud, the prima facie case of anticipation must still fail.

A joint optimization of non-binary variables, such as "statistical risk" and "economic parameters" does not operate as a simple Boolean filter, which is apparently what is disclosed in Mayaud and represented in Fig. 11. Therefore, only by artificially constraining the "statistical risk" to a binary decision, and then using this decision to implement a simple filter, does the Examiner approach the present claim scope by analogy to Mayaud. In fact, there is simply no support for using statistical variables in the system described by Mayaud. The independent claims therefore require a determination of a description of some probability, rather than a presumed certainty, as is the case with the "Drug Allergies" of Mayaud.

Another approach is to consider whether Mayaud can indeed operate on the defined statistical risk parameter presented; that is, whether the optimization of the statistical risk and economic parameters defined by the claims is taught by Mayaud. The Examiner trivializes the determined "statistical risk" to a medical certainty. However, the statistical risk is employed *after* determination, and in order to anticipate the claims, an input of the form defined by the claims should be usable. Thus, it is clear that the use of the phrase "statistical risk" in the claims, may, for example, represent a 50% probability. However, Mayaud teaches no capacity to receive, handle or process such an input, or to perform any optimization or analysis of this type of value. For example, if there is a 50% probability that the patient is allergic to Penicillin, how does the doctor input this representation, and what does the output look like? Since the plain meaning of the claim language is inconsistent with the Examiner's claim interpretation, that interpretation must be rejected.

The Examiner comments that applicant has not addressed the rejections specifically as formulated by him, and in particular failed to focus on the sections of the Mayaud reference cited. Mayaud, Col. 39, line 44-Col. 40, line 37 state:

> Further to enhance the prescribing decision process, additional features can be included on screens such as FIG. 7, for example drug pricing information, employing actual wholesale or retail pricing, or comparative pricing or on another manner of drug pricing or grouping, such as a comparative scale or price rating system, or relative pricing based on actual prescription benefit management company contracts. Such pricing information can greatly influence M.D. decision-making, improving formulary compliance and reducing overall drug costs, without restricting a physician's choices.

A powerful optional feature of the invention is shown in exemplary fashion by the drug evaluation screen depicted in FIG. 11. After a physician selects a drug block 121 from one of the screens of FIGS. 7 to 10, the system can optionally scan a drug preference database of preferred drug treatments block 71 and the selected patient's history record for an evaluation of the merits of the selected drug in treating the condition in general and for this selected patient. The drug preference database may be remote and may be maintained, for example, by a managed care organization, HMO, or prescription benefits management company. As the FIG. 11 example shows (which example employs different condition and drug selections from those used in FIGS. 6 and 7) one possible result of the database scan may be an on-screen report with an alert message, in header 126 advising the physician that the selected drug is "Not a first line drug" for treating the selected condition. As a helpful suggestion to the physician the system can also offer alternative drugs, from listings in the drug preference database, as being more meritorious for the treatment of the condition in question (pursuant to the maintaining benefit company's standards or, preferably, to objective literature reports).

To this end, the drug selection evaluation block 169 screen of FIG. 11 comprises an explanatory box 128 elucidating header 126; an alternative drug selection menu 130; and at the bottom of the screen, three action buttons; for example, Tx Guidelines 132 to access treatment information about the alternative drug highlighted in menu 130; a confirm button 134 to post the physician's original drug selection, in this case "Cefixime" and to return to prescription creation screen 39; and a cancel button 136 which returns the user to the drug-selection of FIG. 7.

The treatment information available via Tx Guidelines button 132 may include a literature reference supporting the system's finding that Cefixime is not a preferred first line agent for treatment of the selected condition, otitis media. Optionally there may be a selection on a drop-down menu from the Tx Guidelines button 132 enabling a physician, without further effort to have a copy of such a study sent to them. In a further optional embodiment, Tx Guidelines button 132 can provide the user with an access point to full disclosure and prescribing information on the drug. Available treatment guidelines information can include details of the particular conditions for which a system suggested alternative drug has been found effective, adverse conditions, preferred dosages and administration routes, literature sources and so on. This aspect of the inventive system provides a simple, nonintrusive technique for bringing new drug information to physicians at a critical moment of need, when creating a prescription.

As best understood by applicant, the system described by Mayaud provides a drug preference database which presents to a physician a preferred drug or drugs based on patient disease information and certain types of pricing information. As discussed above, there does not appear to be any statistical risk or risk analysis, nor any joint optimization. Note, for example, that the drugs presented in Figs. 7 and 11 are merely in alphabetical order. Mayaud provides no teaching which would enable a person of ordinary skill in the art to practice the technology claimed by applicant to optimize these lists further based on the specified parameters. While Mayaud apparently proposes a system for improving drug prescription management, e.g., Col. 4,

lines 20-34, it fails to particularly teach the present claim elements, which is the focus of the Board's adjudication.

It is noted, e.g., with respect to claims 30 and 45, that a dependent claim adopts the limitations of the parent claim, and therefore the interaction of the dependent claim and the parent claim is relevant to a discussion of the patentability thereof.

Likewise, the same object or step cannot correspond to different claim elements. Thus, the "statistical risk" of claim 29 cannot be the same as the "risk tolerance" of claim 31 (see also claim 62); yet, the Examiner alleges that the allergy information satisfies both. The use of tortured phraseology, such as "allergy … indicating *intolerance* toward the allergen" does not remedy the fact that there is no discussion of either statistical risks or risk tolerance in Mayaud.

With respect to claims 33 and 48, it is noted that the "cost optimization" alleged to be taught by Mayaud is nowhere described in the reference. It appears that any such "cost optimization" is performed during data entry and database preparation, and represents a static determination of "value" which is not thereafter subject to a joint optimization as required by the claims.

Claim 36 provides that the "presented set of records [is further optimized] based on the determined user preference". There appears to be no user preference consideration in an optimization taught and enabled by Mayaud.

With respect to claim 49, there appears no basis in Mayaud to presume that the *order* of the drugs in Fig. 11 is anything other than alphabetical (Amoxicillin, Trimethoprim/Sulfa), and there is no express or implicit teaching that the output is a sorted list of the set of records having an *order* dependent on the determined economic parameters and the determined statistical risk.

The rejection of claim 50 remains indistinct, due to tautology.

Examiner states that Col. 19, line 30 anticipates claim 62, which provides "The method according to claim 59, further comprising the steps of providing a plurality of relevance profiles, and selecting a relevance profile to define a risk tolerance." Col. 19, lines 17-34, reads as follows:

> Patient features bar 40 comprises a Select Patient button 46, a selected patient indicator 48, in this case Mary Harrington, a patient Problems button 50 and a patient Allergies button 52. Beneath Problems button 50 are displayed Mary Harrington's currently active problems 51 or conditions, shown here as pharyngitis and bronchitis. Beneath Allergies button 52 are displayed Mary Harrington's known allergies. Pressing or otherwise activating Problems button 50 or Allergies button 52 access the remote database for the

patient's history and, opens a window or screen listing problems or allergies from which a physician, or other professional user, can select new problems or allergies to add to Mary Harrington's record, or delete ones that are no longer active. **Optionally, system-provided problem or allergy libraries may be organized into multiple lists with button 50 or 52, respectively, opening a list selection box as a preliminary to displaying a selected problem or allergy list.**

There is not believed to be any disclosure that a selection of one of a plurality of "relevance profiles" (if met at all by these "problem" or "allergy" libraries), are selected to define a "risk tolerance". Thus, the Examiner has apparently trivialized express claim language in order to shoehorn disparate disclosure to support an anticipation rejection.

Claim 64 further comprises the steps of providing a client terminal having an interface for the user, providing a server for receiving information from the user and optimizing the presented records, and communicating between the client terminal and server over a computer network. While, in general, client-server computing systems are known, and indeed Mayaud discloses clients 201 and a server 206, the present claim describes that the optimization is performed at the server, thus distinguishing Mayaud which provides not such teaching.

It is therefore believed that the rejections of the Examiner should be reversed.

Respectfully submitted,

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Coauthor of "**Statistical Risk** Assessment: Old Problems and New Applications," Crime and Delinquency (January 2006). Andrew J. Harris **...**
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United States Court of Appeals for the Federal Circuit

04-1562, -1563, -1589

IN RE OMEPRAZOLE PATENT LITIGATION

ASTRA AKTIEBOLAG, AKTIEBOLAGET HASSLE,
ASTRA MERCK ENTERPRISES INC., ASTRA MERCK INC.,
KBI-E, INC., KBI, INC., and ASTRAZENECA LP,

Plaintiffs-Cross Appellants,

v.

ANDRX PHARMACEUTICALS, INC.,

Defendant-Appellant,

and

GENPHARM, INC., KREMERS URBAN DEVELOPMENT CO.,
and SCHWARZ PHARMA, INC.,

Defendants.

Errol B. Taylor, Milbank, Tweed, Hadley & McCloy LLP, of New York, New York, argued for plaintiffs-cross appellants. With him on the brief were Fredrick M. Zullow and Lawrence T. Kass; and Jay I. Alexander, of Washington, DC. Of counsel were John M. Griem,Jr. and Claire A. Gilmartin.

Margaret A. Dale, Proskauer Rose LLP, of New York, New York, argued for defendant-appellant. With her on the brief were Louis M. Solomon and Jeremy R. Kasha. Of counsel on the brief were James V. Costigan and Martin P. Endres, Hedman & Costigan, of New York, New York.

Appealed from: United States District Court for the Southern District of New York

Judge Barbara S. Jones

United States Court of Appeals for the Federal Circuit

04-1562,-1563,-1589

IN RE OMEPRAZOLE PATENT LITIGATION

ASTRA AKTIEBOLAG, AKTIEBOLAGET HASSLE,
ASTRA MERCK ENTERPRISES INC., ASTRA MERCK INC.,
KBI-E, INC., KBI, INC., and ASTRAZENECA LP,

Plaintiffs-Cross Appellants,

v.

ANDRX PHARMACEUTICALS, INC.,

Defendant-Appellant,

and

GENPHARM, INC., KREMERS URBAN DEVELOPMENT CO.,
and SCHWARZ PHARMA, INC.,

Defendants.

DECIDED: April 23, 2007

Before NEWMAN, RADER, and BRYSON, Circuit Judges.

Opinion for the court filed by Circuit Judge RADER. Opinion concurring in part and dissenting in part filed by Circuit Judge NEWMAN.

RADER, Circuit Judge.

Astra Aktiebolag, Aktiebolaget Hässle, Astra Merck Enterprises Inc., Astra Merck Inc., KBI-E Inc., KBI Inc., Astra Pharmaceuticals L.P., and AstraZeneca L.P. (collectively Astra) filed patent infringement suits against several pharmaceutical

companies that were seeking permission from the Food and Drug Administration (FDA) to market generic versions of Prilosec®, Astra's gastric acid inhibiting drug. The United States District Court for the Southern District of New York tried the case in four phases. Following a fifty-two day bench trial, the district court decided in Phases I and III that Andrx's product infringes two of Astra's patents, U.S. Patent Nos. 4,786,505 (the '505 patent) and 4,853,230 (the '230 patent). Astra Aktiebolag v. Andrx Pharm., Inc., 222 F. Supp. 2d 423 (S.D.N.Y. 2002). This court affirmed that judgment. In re Omeprazole Patent Litig., 84 Fed. App'x. 76, 2003 WL 22928641 (Fed. Cir. 2003) (Omeprazole II).

This appeal involves Phases II and IV of the same litigation. The district court entered a final judgment finding that Andrx Pharmaceuticals, Inc. (Andrx) literally infringed claims 1, 2, 3, 7, 9, 16, and 20-21 of Astra Aktiebolag's United States Patent No. 6,013,281 (the '281 patent). The trial court also entered several other judgments about the enforceability of that patent and other Astra patents. In re Omeprazole Patent Litig., M-21-81 (BSJ), MDL Docket No. 1291 (S.D.N.Y. July 15, 2004) (Final Judgment). At the same time, however, the district court also found the asserted claims of Astra's '281 patent anticipated or obvious. Final Judgment, slip op. at 2. Detecting no error of law or fact, this court affirms.

I

Phases I and III of this case produced judgments of patent infringement against Andrx and other defendants. This case, however, involves only the '281 patent and one defendant, Andrx. As set out in the district court's thorough 38-page opinion, Phase II involves infringement and validity of the '281 patent; Phase IV involves Andrx's defenses of inequitable conduct and unclean hands. In re Omeprazole Patent

Litigation, M-21-81 (BSJ), MDL Docket No. 1291 (S.D.N.Y. May 19, 2004) (Omeprazole III). In addition, unlike the patents that claimed a formulation in Phases I and III, the '281 patent claims only a process.

Omeprazole is the generic name for Prilosec®. Astra Aktiebolag v. Andrx Pharm., Inc., 222 F. Supp. 2d 423, 433 (S.D.N.Y. 2002) (Omeprazole I). Omeprazole inhibits the production of gastric acid through a unique mechanism. Id. at 434. After a complex absorption process, Omeprazole transforms into its active species in the parietal cells (acid-producing cells in the stomach lining) and inhibits acid production. Id. However, omeprazole degrades in acidic and neutral environments. Therefore, it must be protected from contact with gastric juices while traveling to the parietal cells. Omeprazole III, slip op. at 3. Thus, an omeprazole formulation needs a protective enteric coating around the core containing the active alkaline reacting compound (ARC) and a separating layer between that core and the coating. Id.

The '281 patent recites a method for making this pharmaceutical formulation. The pharmaceutical formulation is composed of a core that contains a proton pump inhibitor like omeprazole to decrease gastric acid secretion, a water soluble separating layer, and an enteric coating layer. '281 patent, Abstract. Specifically, the '281 patent recites a process for creating the separating layer by causing an in situ reaction involving the enteric-coating material and the ARC in the core. Omeprazole III, slip op. at 4. The reaction creates a salt form of the enteric-coating polymer between the core and the enteric-coating layer. Id. Thus, the '281 process produces an omeprazole formulation with three distinct layers, but starts with only two of the three layers. Id.

This in situ reaction requires a specific ARC concentration in the core. Claim 1, for example, requires more than 0.1 mmol/g dry ingredients in the alkaline-containing core:

> 1. A process for preparing an oral pharmaceutical formulation comprising the steps of:
>
> forming a core material comprising a proton pump inhibitor and at least one alkaline reacting compound [ARC], wherein the concentration of the alkaline reacting compound is about 0.1 mmol/g dry ingredients in the alkaline containing part of the core material, and
>
> applying an enteric coating polymer layer so as to surround the core material thereby forming in situ a separating layer as a water soluble salt product between the alkaline compound and the enteric coating polymer.

'281 Patent col.15 l.65 – col.16 l.9. The remaining claims all depend upon claim 1. Claim 9, which the district court found obvious, recites:

> 9. The process according to claim 1, wherein the alkaline reacting compound is an alkaline salt of phosphoric acid, carbonic acid or silicic acid.

'281 Patent col.18 ll.3-5. The '281 process adjusts the variables during the enteric-coating process to account for the particular enteric coatings. Omeprazole III, slip op. at 4. The '281 patent states that "process parameters such as inlet air temperature, air flow, atomizer air flow and spraying rate are adjusted with respect to the equipment used for the process as well as the specific enteric coating polymer(s)." '281 Patent col. 8 ll.51-55. For example, when using hydroxypropyl methylcellulose acetate succinate LF (HPMCAS LF) for applying the enteric coating to a tablet, in the specification under "Examples," the patent states:

> 100 grams of . . . core material . . . was film-coated . . . as described below . . . . The dispersion was fed with a rate of 3.8 g/min. Inlet air temperature used was was 42 °C[sic] and flow was set to 40 Nm^3/h. Atomizing airflow used was 2.1 Nm^3/h, obtained with a pressure of 1.7 bar.

'281 Patent col.11 ll.41-65. After enteric coating, the specification also specifies an increase in the inlet air temperature to 60 °C for approximately five minutes. Id.

The '281 patent issued in the United States on January 11, 2000, with priority back to the February 9, 1995, Swedish application. However, in 1993, before Astra's Swedish filing, a Korean company, the Chong Kun Dan Corporation (CKD), began selling a form of omeprazole under the name "OMP" in Korea. CKD had filed an application (CKD Patent Application) with the Korean Intellectual Property Office (KIPO) for its OMP formulation. The CKD Patent Application became public at KIPO on April 20, 1993. Omeprazole III, slip op. at 2. As a result, Astra questioned CKD about infringement of its Korean process patent for manufacturing omeprazole, a foreign sister to portions of Astra's '505 (Astra's Korean Patent), which issued on November 22, 1988. CKD denied infringement in reliance on its own "unique know-how and . . . patents." CKD's Korean patent publications described compositions with no enteric coating processes. CKD maintained its enteric coating process—its "know how"—as a trade secret.

Astra filed suit in Korea against CKD for infringement. CKD initiated a proceeding in the KIPO, called a "negative confirmation of scope proceeding," seeking an advisory opinion that its process did not infringe Astra's Korean Patents.

This Korean Litigation and its associated KIPO proceedings turned on whether CKD's OMP product contained a subcoating. CKD relied on its two-step process to avoid Astra's Korean '505 patent. This two-step method – variously referred to in the documents as "Method A," method "No. (Ga)" or method "(Ka)ho" (collectively Method A) -- did not involve a separate third step to make a sub-coating. CKD's description of

Method A included core ingredients (omeprazole, arginine, microcrystalline cellulose, SLS, corn starch and magnesium stearate) and enteric coating ingredients (HPMCAS, ethyl citrate, talc, and sorbitan sesquioleate), but no enteric coating process conditions. Then, in September 1993, CKD submitted a modified list of ingredients for the Method A process, which added the coating agent "HPMC grade 2910," but still provided no enteric coating process conditions. The '505 patent required a separate application of a subcoating. Omeprazole I, 222 F. Supp. 2d at 444-47. To verify CKD's denials of any third sub-coating application step, Astra conducted various experiments on CKD's product. Astra's investigations and testing of CKD's batches MA00200 and MA00400 led Astra to repeatedly conclude that CKD's product in fact contained a subcoating. Thus, the Astra inventors continued to believe that CKD actually applied a conventional separating layer.

Thereafter, in June 1994, two of Astra's '281 patent inventors, Dr. Kurt Lövgren and Johan Lundberg, Ph.D., postulated instead that neutralizing enteric coating materials may produce a reaction in situ. With this new theory and the conflicting CKD information as a backdrop, Drs. Lundberg and Lövgren conceived the idea of forming a separating layer from enteric coating material neutralized by the ARC during the coating process. During their experiments to create an in situ separating layer, Drs. Lundberg and Lövgren did not know CKD's process for its product.

After much experimentation, on December 15, 1994, Dr. Lundberg developed the process conditions for making an in situ separating layer. Using process conditions, which included lower inlet air temperatures than those used during previous failed experiments, the latest experiments revealed that a separating layer would surprisingly

form at a lower termperature, 42 °C, than previously used. This work became the foundation of the '281 patent.

Then, on December 21, 1994, for the first time, Dr. Lundberg received the process conditions for making CKD's omeprazole product. CKD's protocol for batch NA01200 required an enteric coating inlet air temperature of 70 °C—a temperature that, in Astra's tests, did not form in situ subcoatings. Testing also showed that batch NA01200 differed from earlier produced CKD products (MA00200 and MA00400). Then, in its December 1994 disclosure, CKD changed its September 1993 protocol. These changes added sorbitan sesquioleate and HPMC to its enteric coating recipe.

Finally, on January 5, 1995, Dr. Lundberg coated tablet cores with ingredients matching CKD's NA01200 batch record, employing his own process conditions, i.e., a processing inlet air temperature of 42 °C, and not the 70 °C temperature required by CKD's protocol. In an "In-House Pharmaceutical Report," Dr. Lundberg reported that all of the in situ separating layers from water-based enteric coatings formed at inlet air temperatures of 42 °C or lower.

On October 6, 1996, Astra Aktiebolag filed United States Application Number 09/413,521 (the '521 application), later issued as the '281 patent. On December 19, 2000, the United States Patent and Trademark Office (PTO) examiner issued an office action rejecting claims 1 through 20 of the application. On March 22, 2001, Astra filed a preliminary amendment to claims 21 through 52. In April, the PTO examiner allowed claims 21 through 52. Then, on July 20, 2001, the applicants submitted a petition to withdraw the '521 application from issuance and to submit an information disclosure statement. With the information disclosure statement, the applicants disclosed five

documents with descriptions of the Korean proceedings (the Korean Information). After considering the Korean Information in September of 2001, the PTO examiner issued a notice of allowance on September 24, 2001. In the notice of allowance, the PTO examiner indicated that the claims were all patentable over the Korean prior art.

Meanwhile, CKD consistently represented to Astra, the applicant inventors, and the Korean courts that its product did not have, or need, a separating layer because CKD used a large amount of the specialized alkaline compound, arginine. In making this representation, CKD relied on its testing of CKD's batch NA01200 and the report of an outside expert, Dr. Jong-Kuk Kim, who viewed a production run for batch NA01200. The CKD Patent Application purports to disclose an omeprazole formulation whose stability relies on the zwitterionic amino acids (like arginine) in the core. The CKD Patent Application does not disclose any enteric coating process conditions or the basic details concerning enteric coatings. Notably, the CKD Patent Application expressly disavows the presence of a separating layer. CKD told the Korean court that its product also did not have a separating layer.

II

The district court found that Andrx literally infringed Astra's '281 patent. Omeprazole III, slip op. at 14-18. Indeed, Andrx admitted that its process met all but one portion of claim 1 of the '281 patent—the portion requiring in situ formation of a separating layer. Id., slip op. at 12. Regardless, Andrx disagrees with the district court's construction of "a water soluble salt" in claim 1. '281 Patent col.5 ll.42-43.

The infringement analysis proceeds as a two-step process: claim construction, followed by comparison of the claims to the accused device. N. Am. Container, Inc. v.

Plastipak Packaging, Inc., 415 F.3d 1335, 1344 (Fed. Cir. 2005). This court reviews claim construction without deference, Cybor Corp. v. FAS Tech., Inc., 138 F.3d 1448, 1455 (Fed. Cir. 1998), and infringement for clear error, Power Mosfet Techs., L.L.C. v. Siemens AG, 378 F.3d 1396, 1406 (Fed. Cir. 2004).

Andrx argues that the district court erred in finding that its product infringes the '281 patent because it does not have a water soluble separating layer, but instead a layer composed of "almost 50% talc." According to Andrx, its separating layer with talc is not water soluble, but only disintegrates in water. Andrx asserts that disintegration is not soluble. Indeed, the '505 and '230 patents claim a "subcoating which rapidly dissolves or disintegrates in water" and a "subcoating which is soluble or rapidly disintegrating in water," respectively. Omeprazole I, 222 F. Supp. 2d at 446.

The '281 patent indeed claims "a water soluble salt." '281 Patent col.16 l.8. The district court correctly discerned that this language permits the inclusion of talc. The language of claim 1 does not claim a separating layer that is water soluble. Claim 1 instead recites a salt product that is water soluble. The '281 patent specification, under "Summary of the Invention," describes the separating layer as comprising "a water soluble salt of an enteric coating polymer." '281 Patent col.5 ll.42-43 (emphasis added). A sentence later, the patent specification states: "a separating layer comprising a water soluble salt of an enteric coating polymer is obtained." '281 Patent col.5 ll.48-49 (emphases added). In addition, example 1 (and 4-7) of the '281 patent employs an enteric-coating layer that contains HPMCAS as well as triethylcitrate, sodium laurylsulphate, and talc. '281 Patent col.8 l.65 - col.9 l.51. Thus, the district court

correctly interpreted the '281 patent claim to permit inclusion of talc in the separating layer.

The trial court did not err by referring to the Omeprazole I opinion, which covered Phase I, because it pointed to a portion of its opinion that discussed the water solubility of the salt of the enteric coating. In Phase I, the district court found

> that the HPMCP-salt layer is film-forming and "soluble or rapidly disintegrating in water" as that phrase is used in the '505 and '230 patent claims . . . [and that] the presence of talc does not affect this court's finding that the HPMCP-salt subcoating is soluble in water—it is expressly listed as an appropriate ingredient in the patents. (citations to record omitted).

222 F. Supp. 2d at 539 (emphasis added). This finding applied correctly to the '281 patent claims that do not require that the entire separating layer be water soluble, but only that the salt product be water soluble. In discussing the entire subcoating, the district court noted that the presence of talc does not affect the solubility of the salt. Id. In addition, the district court found in Phase II, that "[p]ersons skilled in the art would understand that each of those components [such as talc] are also present in the in situ layer generated by the claimed process, as well as in the enteric-coating layer." Omeprazole III, slip op. at 11-12. Indeed, the district court received testimony in Phase II that the contents of the enteric coat would inevitably become a part of the separating layer's salt because it is the result of a reaction between the HPMCP, which converts to a salt, in the enteric coat and the core, which contains an alkaline reacting compound:

> Dr. Davies explained that the salt layer is the result of a reaction between the HPMCP in the enteric-coating material and the DHP in the active layer. The talc from the enteric-coating spray remains in the HPMCP-salt layer when the HPMCP converts to the salt. (Davies Tr. 992:16-993:4 ("Talc is placed on the product in the enteric coating layer. It is still present during the formation of the HPMCP salt layer. . . . [The] salt layer [and] the enteric coating layer both contain talc.").)

Omeprazole I, 222 F. Supp. 2d at 530. Therefore, even though the district court was comparing Andrx's product to the '505 and '230 patent claims, those claims, likewise, recite a water soluble salt product despite the presence of a talc during its formation. In addition, the '281 patent's five preferred embodiments clearly state that they contain talc. As shown in testimony, the talc would still be present in the formation of the separating layer's salt-product. Thus, the district court did not err in its claim construction or its conclusion that Andrx's product infringed the '281 patent.

III

The district court found that the CKD patent application anticipated claims 1, 2, 3, 7, 16, and 20-21 of the '281 patent. Omeprazole III, slip op. at 2. The CKD patent application became public on April 20, 1993, id., slip op. at 20, and contained all of the elements claimed in the anticipated claims. That application also disclosed the exact proportions of the principal ingredients in the '281 patent's example 1. Omeprazole III, slip op. at 7. The only '281 "limitation" missing from the Korean application is the language "thereby forming in situ a separating layer."

Anticipation requires disclosure of each and every claim limitation in a single prior art reference, either explicitly or inherently. MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed. Cir. 1999). An anticipation analysis requires a comparison of the construed claim to the prior art. Helifix, Ltd. v. Blok-Lok, Ltd., 208 F.3d 1339, 1346 (Fed. Cir. 2000).

Astra asserts that the claim limitation, "forming in situ a separating layer," is not found in the CKD Patent Application. Astra also contends that the '281 patent contains

an additional limitation requiring performance of the claimed process at a temperature below 42 °C.

At the outset, the asserted 42 °C "limitation" is only an example from the specification. Absent some clear intent to the contrary, this court does not import examples from the specification into the claims. Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1571 (Fed. Cir. 1988) ("[E]mbodiments and examples appearing in the specification will not generally be read into the claims."). The 42 °C "limitation" does not appear in the claims. Moreover, the specification suggests variable temperatures, not a 42 C° requirement: "The process parameters such as inlet air temperature, air flow . . . are adjusted with respect to the equipment used as well as the specific enteric polymer . . . ." '281 Patent col.8 ll.51-57. Thus, the district court did not err in refusing to read Astra's alleged 42 °C limitation into Claim 1 of the '281 patent.

The "in situ formation of a separating layer" limitation presents a more difficult issue. The CKD patent application does not explicitly recite this feature. Therefore, anticipation turns on whether the CKD application inherently disclosed "in situ" formation. The CKD application disavowed a subcoating and disclosed no process conditions to form a separating layer in situ.

Nonetheless, in finding inherent anticipation, the district court relied on and set out in its opinion the assertions Astra made during the Korean Litigation and KIPO proceedings:

- that the CKD process (Method A) claimed in the CKD Patent Application resulted in the in situ formation of a separating layer in CKD's OMP tablet, Omeprazole III, slip op. at 29;
- that Method A forms a separating layer, even though Method A does not have a separate step of applying the separating layer, id., slip op. at 30;

- that Method A formed a separating layer and that such formation is inherent in the process of Method A, id., slip op. at 30-31;
    - "The construction of the inner coating layer formed in Method A is exactly that of the inner coating layer claimed in [the '505 patent]," id., slip op. at 31;
    - "[u]ltimately Method A contains the inner coating layer process," id.;
    - "the inner coating layer of the 'OMP tablet' is created instantly at the point of time when the substance of coating the enteric coating is sprayed," id.;
    - According "to the content of the Expert opinion . . . with the start of the process of the enteric coating of the OMP tablet, HPMCAS, which is an enteric coating substance, instantly reacts with the L-arginine that is in the core and forms a thin membrane, i.e., an inner coating layer," id.;
- Dr. Lövgren contended that the CKD process resulted in the formation of a separating layer, id.;
- C.T. Rhodes, Ph.D., who Astra relied on in the proceedings in Korea against CKD, opined that the CKD product contained an in situ layer, id..

Astra does not deny these statements. Furthermore, as noted by the district court: "If Astra had scientific proof with which to rebut or refute its prior admissions of inherency, it surely would have put on such proof. Astra did not." Id., slip op. at 32. Furthermore, Dr. Umesh Banakar, Andrx's expert, testified that if a formulator followed the CKD process as described in the CKD Patent Application, the separating layer would form in situ "each and every time." Id., slip op. at 29. In addition, the district court accorded "little if any weight" to Astra's contrary expert testimony from Dr. Robert Langer's testimony, in part because Astra did not provide Dr. Langer "with any of the submissions (including test results) on which Astra relied in Korea to prove that the formation of a separating layer naturally results from the CKD process." Id. The district court acting as factfinder found credible that evidence of inherent in situ formation, and we find no clear error in that determination. The district court did not settle for proof that in situ formation could result from the CKD process, as is suggested in the dissent; rather, the district court credited evidence that in situ formation does result from the CKD process.

As noted, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency. See In re Cruciferous Sprout Litig., 301 F.3d 1343, 1349 (Fed. Cir. 2002). Moreover, "[i]nherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art." Id.; Schering Corp. v. Geneva Pharms., 339 F.3d 1373, 1377 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition in the prior art). Though Drs. Lövgren and Lundberg may not have recognized that a characteristic of CKD's Method A ingredients, disclosed in the CKD Patent Application, resulted in an in situ formation of a separating layer, the in situ formation was inherent.

The record shows formation of the in situ separating layer in the prior art even though that process was not recognized at the time. The new realization alone does not render that necessary prior art patentable. Id. (citing Atlas Powder, 190 F.3d at 1347) ("[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's function, does not render the old composition patentably new to the discoverer."); Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1376 (Fed. Cir. 2001) (explaining that newly discovered results of known processes are not patentable because those results are inherent in the known processes); Verdegaal Bros., Inc. v. Union Oil & Co. of Cal., 814 F.2d 628, 633 (Fed. Cir. 1987) (holding that the recognition of a new aspect of a known process is not a patentable invention of a novel process). Despite CKD's denials, Drs. Lövgren and Lundberg realized and explained that CKD's OMP tablet's formation of a separating layer was a natural result flowing from the combination of certain ingredients listed in

Method A. That explanation, however, does not make that prior art patentable. The ingredients and protocols CKD gave to the KIPO and Astra in 1993 and 1994 necessarily resulted in in situ formation of a separating layer. Thus, the trial court correctly found inherent anticipation.

IV

Claim 9 of the '281 patent is dependent on claim 1. Claim 9 claims the ARC as an alkaline salt of phosphoric acid, carbonic acid, or silicic acid. The district court found that, in light of the CKD Patent Application, it would have been obvious to a person of ordinary skill in the art to substitute the alkaline salts called for by claim 9 of the '281 patent for the arginine disclosed in the CKD Application. In other words, the district court concluded that it would have been obvious to substitute one ARC for another. Omeprazole III, slip op. at 35. Obviousness under 35 U.S.C. § 103 is a legal conclusion based on underlying factual determinations. Medichem, S.A. v. Rolabo, S.L., 437 F.3d 1157, 1164 (Fed. Cir. 2006).

CKD's patent application coats a core containing an amino acid or an alkali salt of omeprazole as the "basic part" or "alkali reaction component." Id. The district court (and the Korean Appellate Court) found that the CKD application lists arginine as the "basic part" of the core and, alternatively, L-arginine as "an alkali substance." Id. at 35; (Korean) Appellate Trial Court Decision at 3, In Re Omeprazole Patent Litig., Appeal Nos. 04-1562, 04-1563, 04-1589 (Fed. Cir. Aug. 13, 2004). Before the appellate court in Korea, Astra conceded that "L-arginine is generally known as an alkaline reactive compound." Id., Astra's Supplement of the Reasons for the Request for Appeal (to Korean Appellate Court), at 8. Astra also acknowledged that its patented invention

could easily "substitute alkaline reactive compounds [for the] L-arginine in Method A." Id. at 7-8.

The record shows that Dr. Banakar testified that it would have been obvious to a person of ordinary skill in the art of pharmaceutical formulation to replace the arginine in the CKD application with an alkaline salt of phosphoric acid, carbonic acid, or silicic acid. As Dr. Banakar noted, all such substances are ARCs that can stabilize omeprazole. Omeprazole III, slip op. at 36. The district court noted that "Dr. Banakar's testimony is corroborated by Astra's own admissions that arginine is 'just like' other ARCs and 'it is easy to substitute' arginine for another ARC." Id.

Astra countered that these statements in the Korean proceedings "addressed whether arginine can function as an ARC stabilizing agent in the context of the Korean '505 sister patent - not the '281 patent at issue." However, Astra still admitted that an ARC could easily replace CKD's L-arginine. Therefore, this court finds no clear error in the district court's factual findings and no error in its conclusion that it would have been obvious to one skilled in the art to substitute one ARC for another. Therefore, claim 9 of the '281 patent would have been obvious at the time of invention.

V

Andrx argues the district court erred in declining to find the '281 patent unenforceable through inequitable conduct and fraud on the PTO and in denying its claim for attorney fees under 35 U.S.C. § 285. Andrx also states in its brief that it "is entitled to a ruling on its counterclaims" and that "the district court must rule on the inequitable conduct and fraud claims for the determination of attorney fees under 35 U.S.C. § 285." Appellant's Br. at 51. The district court did not entertain Andrx's

inequitable conduct and fraud defenses because it considered them "mooted by [its] rulings that each of the asserted claims of the '281 patent is invalid." Omeprazole III, slip op. at 37. The district court did consider Andrx's "unclean hands" argument, but found no evidence to support a finding of "unclean hands." Id., slip op. at 39. This court reviews an ultimate inequitable conduct determination for abuse of discretion and the underlying determinations including materiality and intent under the clearly erroneous standard. Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995). Andrx bears the burden of proving by clear and convincing evidence that Astra acted with unclean hands. See generally 6 Donald S. Chisum, Chisum on Patents: A Treatise on the Law of Patentability, Validity, and Infringement § 19.03[5] (2001).

Andrx's "unclean hands," fraud, and inequitable conduct arguments were much more limited before the district court than as presented to this court. Before the district court, Andrx raised an "inventors' oath" argument claiming that the '281 inventors were not truly the inventors of the process claimed in the '281 patent. On inequitable conduct during prosecution of the '505 and '230 patents, the district court stated:

> After a complete review of the hundreds of pages of proposed findings of fact and conclusions of law submitted by Andrx in support of its unclean hands theory, the court is utterly unpersuaded.

Omeprazole III, slip op. at 37-38. As evidence of unclean hands, Andrx asserted "(1) delay of trial; (2) affirmative use of tainted evidence; and (3) withholding significant documents until after the Phase I and II trials were completed." Id., slip op. at 37. The district court attributed delay equally to Andrx and Astra. Furthermore, the trial court noted that Andrx, not Astra, requested that the '281 patent be tried with the '505 and '230 patents. Id., slip op. at 38. Now before this court, Andrx hopes to argue that

Astra's inventors misrepresented facts to the PTO and deliberately failed to disclose the Korean Litigation and KIPO proceedings to the PTO. This court need not reach issues Andrx did not raise properly in proposed post-trial findings before the District Court. Viskase Corp. v. Am. Nat'l Can Co., 261 F.3d 1316, 1326 (Fed. Cir. 2001).

The district court stated that it would "not make detailed findings concerning Andrx's additional defenses pertaining to the '281 patent, which are mooted by this court's rulings that each of the asserted claims of the '281 patent is invalid." Omeprazole III, slip op. at 37. The inequitable conduct claim was not technically moot, because it would have rendered the entire '281 patent unenforceable, rather than just the claims that were held invalid. Nonetheless, the court's ruling on mootness did not prejudice Andrx, because the record contains no support for Andrx's argument that the '281 patent inventors' conduct before the PTO constituted inequitable conduct. Instead, the inventors disclosed the Korean litigation and KIPO proceedings. The PTO examiner had the benefit of this information before allowance of the patent. Furthermore, the record shows that CKD consistently represented to the '281 patent inventors that their omeprazole product did not have a separating layer. Thus, those inventors had every reason to believe that they had invented the process disclosed in the '281 patent. As a result, nothing in the record would support a finding that the inventors engaged in inequitable conduct. The district court did not err or abuse its discretion in finding that Andrx did not show fraud, "unclean hands," or inequitable conduct. Without a finding of inequitable conduct in the first instance, Andrx cannot possibly prevail with its new contentions of "infectious unenforceability" against all patents in suit, including the '230 and the '505 (which were held valid and infringed).

Lastly, in August 2004, after it issued its opinion on the two phases on appeal here, the district court found Astra, not Andrx, the "prevailing party." In re Omeprazole Patent Litigation, M-21-81 (BSJ), MDL Docket No. 1291 (S.D.N.Y. August 8, 2004) (Costs Order). In the words of the trial court, "Astra is the prevailing party because its successes on its affirmative claims far outweigh any gains Defendants made on their counterclaims." Costs Order, slip op. at 3.

This court reviews a denial of attorney fees under 35 U.S.C. § 285 for an abuse of discretion; however, this court reviews the factual determination of whether a case is exceptional under § 285 for clear error. Q-Pharma, Inc. v. Andrew Jergens Co., 360 F.3d 1295, 1299 (Fed. Cir. 2004) In addition, this court reviews the meaning of the term "prevailing party" without deference. Inland Steel Co. v. LTV Steel Corp., 364 F.3d 1318, 1320 (Fed. Cir. 2004) (citing Waner v. Ford Motor Co., 331 F.3d 851, 857 (Fed. Cir. 2003) ("We review de novo whether the district court applied the proper legal standard under 35 U.S.C. § 285, and we review the court's factual findings, including whether the case is exceptional, for clear error.")).

In Phases I and III of this litigation, the district court found most of the asserted claims infringed: (1) Defendant Genpharm, Inc. (Genpharm) literally infringed claims 1, 5, 6, 8, 9, 10, 12, and 14 of the '505 patent; (2) Genpharm literally infringed claims 1, 6, 7, 10, 11, 12, and 13 of the '230 patent; (3) three other defendants, referred to collectively as "Cheminor," literally infringed claims 1, 5, 10, and 14 of the '505 patent; (4) Cheminor literally infringed claims 1, 6, 12, and 13 of the '230 patent; (5) Andrx literally infringed claims 1, 5, 6, 8, and 10 of the '505 patent; (6) Andrx literally infringed claims 1, 6, 7, 10, and 13 of the '230 patent. Omeprazole I, 222 F. Supp. 2d at 432-33.

The district court entered an injunction prohibiting all defendants from marketing their generic omeprazole product through 2007. Costs Order, slip op. at 3. Also, though the district court also found claim 1 of United States Patent No. 5,093,342 (the '342 patent) invalid as anticipated, it found the asserted claims of the '505 and '230 patents not invalid. 222 F. Supp. 2d at 433. The district court found that "the *H. pylori* ['342] patent . . . of much less significance than the formulation ['505 and '230] patents." Costs Order, slip op. at 5. Moreover, in Phases II and IV, the district court also found that Andrx literally infringed claims 1, 2, 3, 7, 9, 16, and 20-21 of the '281 patent. Final Judgment, slip op. at 1. Therefore, this court finds no clear error in the district court's conclusion that this case was not exceptional, and finds no error in the district court's conclusion that Astra was the prevailing party. The district court properly applied the proper standards. Because section 285 allows an award of attorney fees only to the "prevailing party," the district court's conclusion that Andrx cannot recover attorney fees is not an abuse of discretion.

VI

In conclusion, this court affirms the district court's judgment finding that Andrx literally infringed claims 1, 2, 3, 7, 9, 16, and 20-21 of Astra's '281 patent, but that claims 1, 2, 3, 7, 16, and 20-21 of the '281 patent are anticipated and that claim 9 of the '281 patent is obvious. This court also affirms the district court's conclusion that Andrx's counterclaims were mooted, that there was no inequitable conduct, fraud, or unclean hands in Astra's prosecution of the '281 patent, and that Astra's '505 and '230 patents are not unenforceable through "infectious unenforceability."

COSTS

Each party shall bear its own costs.

AFFIRMED

United States Court of Appeals for the Federal Circuit

04-1562, -1563, -1589

IN RE OMEPRAZOLE PATENT LITIGATION

ASTRA AKTIEBOLAG, AKTIEBOLAGET HASSLE,
ASTRA MERCK ENTERPRISES INC., ASTRA MERCK INC.,
KBI-E, INC., KBI, INC., and ASTRAZENECA LP,

Plaintiffs-Cross Appellants,

v.

ANDRX PHARMACEUTICALS, INC.,

Defendant-Appellant,

and

GENPHARM, INC., KREMERS URBAN DEVELOPMENT CO.,
and SCHWARZ PHARMA, INC.,

Defendants.

NEWMAN, Circuit Judge, concurring in part, dissenting in part.

I concur in the court's ruling that the claims are infringed if valid, as well as the rulings on the issues of inequitable conduct, fraud, unclean hands, and attorney fees. However, I cannot agree that the claims of the '281 patent are invalid, for the findings of "inherent anticipation" and obviousness are based on incorrect premises of law.

Applying a novel theory of "inherent anticipation," the court invalidates Astra's patent on a newly discovered chemical process: a process involving known ingredients but different and previously unknown reaction conditions and achieving a different result. Based on a flawed analysis of the law of "inherent anticipation," the court invalidates the patent on Astra's previously unknown process for producing an in situ polymeric sublayer for omeprazole. The court apparently reasons that because the ingredients were known, it is irrelevant that a significant change in conditions produces a result that is different from that achieved under the conditions of the prior art. Such a view of "inherency" is contrary to legal as well as scientific principles.

The court's explanation and citation of authority suggest that my colleagues have confused the law governing patentability of a newly discovered use of a known composition, which is achieved by "process" claim,[1] with the unpatentability of the known composition itself. The claims at issue are not directed to a composition; they are directed to a process for forming a sublayer from known ingredients:

> Claim 1. A process for preparing an oral pharmaceutical formulation comprising the steps of:
>
> forming a core material comprising a proton pump inhibitor and at least one alkaline reacting compound, wherein the concentration of the alkaline reacting compound is about 0.1 mmol/g dry ingredients in the alkaline containing part of the core material, and
>
> applying an enteric coating polymer layer so as to surround the core material thereby forming in situ a separating layer as a water soluble salt product between the alkaline compound and the enteric coating polymer.

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1 35 U.S.C. §100(b) defines "process" as follows: "The term 'process' means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."

The Astra process is not described in the prior art, although Astra admitted that it believed that the Korean company Chong Kun Dan Corporation (CKD) had made such a product. It is not disputed that such a sublayer does not form under the conditions in the CKD patent application. No such reaction is described in CKD's Korean patent application, nor the conditions that could have produced such a product. Nonetheless, my colleagues rule that the process discovered by Astra is "inherently anticipated" by the CKD application. That is not the law of either anticipation or inherency. I must, respectfully, dissent.

"Anticipation" Means Lack of Novelty

Novelty is fundamental to patentability. Lack of novelty, or "anticipation" in patent-ese, means that the subject matter was previously known in terms of 35 U.S.C. §102.[2] While some properties and uses of known compositions may indeed be "inherently anticipated" in that their existence would have been known to persons in the field of the invention, even if unpublished, that is not this situation. No prior art describes the Astra process, and there is no evidence that a person of ordinary skill would have known of its existence. What is unknown cannot "anticipate."

Anticipation requires that "each element of the claim at issue is found, either expressly described or under the principles of inherency, in a single prior art reference or

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2 35 U.S.C. §102 provides that novelty is negated if the invention was known or used by others in the United States, §102(a); or if the invention was patented or described in a printed publication, §102(b); or in public use or on sale, §102(b); or derived from another, §102(f); or the prior invention of another who did not abandon, suppress, or conceal it, §102(g).

that the claimed invention was previously known or embodied in a single prior art device or practice." Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771 (Fed. Cir. 1983). See MEHL/Biophile Int'l Corp. v Milgraum, 192 F.3d 1362, 1365 (Fed. Cir. 1999) (to anticipate, a single reference must teach every limitation of the claimed invention; any limitation not explicitly taught must be inherently taught and would be so understood by a person experienced in the field); In re Baxter Travenol Labs., 952 F.2d 388, 390 (Fed. Cir. 1991) (the dispositive question is "whether one skilled in the art would reasonably understand or infer" that a reference teaches or discloses all of the elements of the claimed invention); Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268-69 (Fed. Cir. 1991) (to anticipate, every element of the claims must appear in a single prior art reference, or if not expressly shown, then demonstrated to be known to persons experienced in the field of technology); In re Samour, 571 F.2d 559, 562 (CCPA 1978) (the key question is whether a single prior art reference "publicly discloses every material element of the claimed subject matter").

The principle of "inherency," in the law of anticipation, requires that any information missing from the reference would nonetheless be known to be present in the subject matter of the reference, when viewed by persons experienced in the field of the invention. However, "anticipation by inherent disclosure is appropriate only when the reference discloses prior art that must necessarily include the unstated limitation, [or the reference] cannot inherently anticipate the claims." Transclean Corp. v. Bridgewood Servs., Inc., 290 F.3d 1364, 1373 (Fed. Cir. 2002) (emphasis in original); Hitzeman v. Rutter, 243 F.3d 1345, 1355 (Fed. Cir. 2001) ("consistent with the law of anticipation, an inherent property must necessarily be present in the invention described by the count, and it must be so

recognized by persons of ordinary skill in the art"); In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999) (that a feature in the prior art reference "could" operate as claimed does not establish inherency).

Thus when a claim limitation is not explicitly set forth in a reference, evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." Continental Can Co., 948 F.2d at 1268. It is not sufficient if a material element or limitation is "merely probably or possibly present" in the prior art. Trintec Indus., Inc. v. Top-U.S.A. Corp., 295 F.3d 1292, 1295 (Fed. Cir. 2002). See W.L. Gore v. Garlock, Inc., 721 F.2d at 1554 (Fed. Cir. 1983) (anticipation "cannot be predicated on mere conjecture respecting the characteristics of products that might result from the practice of processes disclosed in references"); In re Oelrich, 666 F.2d 578, 581 (CCPA 1982) (to anticipate, the asserted inherent function must be present in the prior art).

Applying these principles, it is incorrect to hold that the CKD application "inherently anticipates" the '281 invention. The panel majority contravenes this vast body of precedent, for it is not disputed that no reference explicitly or inherently teaches the process that Astra found to produce an in situ polymeric sublayer. The requirements of inherent anticipation were not met.

Anticipation Also Requires Enablement

To "anticipate," the identical subject matter must not only be previously known, but the knowledge must be sufficiently enabling to place the information in the possession of the public. In Seymour v. Osborne, 78 U.S. 516 (1870), the Supreme Court explained:

> Patented inventions cannot be superceded by the mere introduction of a [prior art reference] unless the description and drawings contain and exhibit a substantial representation of the patented improvement, in such full, clear, and exact terms as to enable any person skilled in the art of science to which it appertains, to make, construct, and practice the invention to the same practical extent as they would be enabled to do if the information was derived from a prior patent. Mere vague and general representations will not support such a defense, as the knowledge supposed to be derived from the publication must be sufficient to enable those skilled in the art or science to understand the nature and operation of the invention, and carry it into practice use. Whatever may be the particular circumstances under which the publication takes place, the account published, to be of any effect to support such a defense, must be an account of complete and operative invention capable of being put into practical operation.

78 U.S. at 555 (emphases added). Precedent illustrates this principle in many areas of technology. See, e.g., Elan Pharmaceuticals, Inc. v. Mayo Foundation, 346 F.3d 1051, 1054-55 (Fed. Cir. 2003) (anticipation requires enablement, whereby the reference "must teach one of ordinary skill in the art to make or carry out the claimed invention without undue experimentation"); Helifix Ltd. v. Blok-Lok, Ltd., 208 F.3d 1339 (Fed. Cir. 2000) (a prior art reference that does not enable a person of ordinary skill in the art to practice the claimed invention does not anticipate the patent claims); Akzo N.V. v. United States Int'l Trade Comm'n, 808 F.2d 1471, 1480 (Fed. Cir. 1986) (anticipation requires that the reference publicly discloses all elements of the claimed invention and enables its practice); Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys., 804 F.2d 659, 665 (Fed. Cir. 1986) (a non-enabling publication is insufficient to anticipate under §102(b), although it may raise §103 issues).

All parties agree that the closest prior art is the Korean CKD application. It was not disputed that the ingredients of the Astra and the CKD omeprazole formulations are the same standard enteric ingredients. Several references describe the use of microcrystalline

cellulose plus an alkaline-reacting compound to formulate pharmaceuticals for drug delivery. However, no reference describes the conditions by which Astra produced an in situ interior sublayer. No reference suggests formulation temperatures at or below 42ºC, or that such a sublayer might form at such low temperatures.

Andrx's expert witness Dr. Banakar agreed that it was not possible to know, from the CKD Korean application, how or if the reaction conditions could be changed so as to produce an in situ sublayer. Although the panel majority states that Dr.Banakar testified that "if a formulator followed the CKD process as described in the CKD Patent Application, the separating layer would form in situ 'each and every time,'" on cross-examination Dr. Banaker admitted that he had conducted no experiments and his conclusion was without verification. He stated that his sole basis for "each and every time" was the Astra argument in the Korean proceedings, the argument that was negated by the evidence in the Korean court, including the testimony of Professor Chung, the Korean court-appointed expert. In all of the proceedings, in Korea and in the United States, it was never disputed that the CKD application does not disclose a separating sublayer, and that such a sublayer does not form in the conditions described for the CKD process. CKD testified in the Korean court that it consistently operated at or near the 70ºC set forth in the CKD Korean application, and that no in situ sublayer was produced.

In the present litigation, the Andrx expert Dr. Banakar testified that specific process conditions are necessary to form an in situ separating layer, that such conditions are different from those set forth in the Korean application, and that his only basis for proposing that the Koreans formed an in situ sublayer was because Astra had unsuccessfully so argued in Korea. Astra states that its argument was based not on information contained in

the Korean patent application or gleaned in the Korean litigation, but on testing of a CKD product. It is not now disputed that the Korean process does not produce a separating sublayer.

By no stretch of fact or law can the Korean application inherently anticipate what it could not produce. A non-enabling reference cannot serve as an invalidating anticipation, either expressly or inherently. My colleagues on this panel, holding otherwise, do not explain how they plug this scientific and legal gap. Such an unexplained finding of inherent anticipation does not add clarity to this jurisprudence.

Secret Information Cannot "Anticipate"

My colleagues speculate that CKD practiced a sublayer-producing process in secrecy, although the Korean inventors denied such practice in the proceedings in the Korean Patent Office and also in the Seoul District Court. Whatever may or may not have been done in secret in Korea does not convert a secret and still unknown process into prior art.

"Anticipating" subject matter must be known, and the knowledge must be sufficient to place enabling information in the possession of the public. See, e.g., Vulcan Eng'g Co. v. FATA Aluminium, Inc., 278 F.3d 1366, 1372-73 (Fed. Cir. 2002) (a secret system that was not known or publicly used in the United States is not prior art and cannot "anticipate"); Woodland Trust v. Flowertree Nursery, Inc., 148 F.3d 1368, 1371 (Fed. Cir. 1998) (secret prior use or knowledge by another is not a bar to patentability).

The Korean court found that an in situ sublayer was not produced by the process set forth in the CKD specification. I repeat, this finding is not challenged by any evidence

presented in this case. Even if CKD indeed practiced a secret process in Korea, and made a sublayer while concealing the process, such an unknown process is not an inherent anticipation.

Patentability of the '281 Process

Astra informed the United States patent examiner that the Korean proceedings included CKD's challenge to the validity of the Korean counterpart of Astra's '281 patent. Astra submitted to the PTO, with English translations, CKD's Korean patent application, Astra's Opposition Statement, the Korean Patent Office's Confirmation of Scope decision of September 25, 1994, Astra's evidence that the CKD product has a separating sublayer, and the Korean district court's ruling that the CKD process does not produce an in situ separating sublayer.

On this background, the United States examiner found that the '281 process was patentable. My colleagues on this panel rely on cases which hold that a known composition cannot be re-patented as a composition when a new property is discovered, citing Atlas Powder, 190 F.3d at 1347, and Bristol-Myers Squibb, 246 F.3d at 1376. That is a correct statement of law, but irrelevant to this case. The '281 claims are not for a known composition; the claims are for a newly discovered process. See Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 875 (Fed. Cir. 1985) (a new process is patentable subject matter, whether or not the product is already known); Atlantic Thermoplastics Co., Inc. v. Faytex Corp., 970 F.2d 834, 841 (Fed. Cir. 1992) ("In the words of the Supreme Court, 'While a new process for producing [a known composition] was patentable, the product itself could not be patented . . . .'" (quoting Cochrane v. Badische Anilin & Soda Fabrik, 111

U.S. 293, 312 (1884))); Ansonia Brass & Copper Co. v. Electrical Supply Co., 144 U.S. 11 (1892). No reference shows the process conditions by which Astra produced the sublayer.

Obviousness of Claim 9

The invalidation of claim 9 is a misapplication of the law of obviousness, for there was no prior art or even general knowledge that suggested that a major lowering of the formulating temperature would cause a polymeric sublayer to form in situ. The court's invalidation of claim 9 appears to be founded on the postulate that CKD had a secret process for making the disavowed sublayer. Accepting that Astra's scientists, Dr. Lovgren and Dr. Lundberg, believed that CKD had made an in situ sublayer and thereby were spurred to experimental investigation, that did not render their success obvious. Obviousness cannot be based on secret or concealed information.

In addition, no references have been cited to suggest that the phosphoric acid, carbonic acid, or silicic acid of Astra's claim 9 should replace the zwitterionic L-arginine in the Korean formulation. And no reference suggested that such a change, combined with a significant temperature reduction, would produce an in situ separating sublayer. Hindsight is not an available analytical mechanism to show obviousness. See Interconnect Planning Co. v. Feil, 774 F.2d 1132, 1138 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time.")

Conclusion

It is apparent that the requirements of "inherent anticipation" are not met. A consistent law, and consistent application, are critical to technological innovation.[3] The panel majority's divergence from precedent not only has led the court to invalidate a fully valid patent, but also brings further uncertainty to this important aspect of patent law.

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3 In summarizing cases showing that Federal Circuit decisions have "oscillated" with respect to inherent anticipation, 1 Chisum on Patents, §3.03[2][c], p. 3-83 (2006) states "some [Federal Circuit panels] stating that recognition is required, others stating that recognition is not required."